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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,594	09/15/2003	Patrick Arnold	LPJ6OXO	1295
22906	7590	01/05/2006	EXAMINER	
MICHAEL BERNS MALONEY, PARKINSON AND BERNS 135 W MAIN STREET URBANA, IL 61801			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,594	Applicant(s) ARNOLD, PATRICK	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-5,7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-15-03</u> . | 6) <input type="checkbox"/> Other: _____ |

A Response/Amendment filed April 29, 2005 is acknowledged. Claim 6 is canceled. New claims 7 and 8 are presented. Accordingly, claims 1-5, 7 and 8 are now under consideration.

A supplemental Response filed September 19, 2005 is further acknowledged.

A missing reference (Tan et al., Biochem. Biophys. Res. Commun.), received by FAX on December 30, 2004, that was cited on an Information Disclosure Statement filed September 15, 2003, is further noted.

Applicant is again requested to provide the publication date of each of the products cited in the Exhibits, or the date at which time each product became available to the public.

Claims 1-6 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not provide enablement for any male. The data provided on page 7 of the specification is limited to those of an age range of 32-40.

Applicant argues the specification is not limited to the one example, but rather illustrates effectiveness for a representative group. Applicant urges so long as the male is capable of producing testosterone, administration of the compound would yield greater testosterone levels without distinction among age groups.

Applicant discusses commercial products, 6-OXO brand nutritional supplements under the ERGO PHARM brand, have achieved commercial success and have been found to be effective for adult males of any age.

Applicant's arguments are not persuasive with respect to claims 1- 3, 5 and 7, and the rejection of record under 35 U.S.C. 112, first paragraph, is maintained.

Art Unit: 1614

In response to Applicant's request for an explanation as to how the specification is not clear with respect to administration to a particular age range, Morales et al., J. Urol. (abstract), and Suzuki et al., Scand. J. Urol. Nephrol. (abstract), are cited to show the state of the art. Morales teaches a progressive decrease in androgen production that commonly occurs after middle age and urges treatment and monitoring in keeping with an unpredictable onset of manifestations that are subtle and variable. Suzuki teaches variability in the ratios of estradiol to total testosterone and free testosterone. It would have been reasonable to expect an increase in the testosterone/estrogen ratio, or an increase in testosterone level independent of an effect on the estrogen level, is unpredictable. Undue experimentation would have been required to practice the methods as instantly claimed.

Applicant is invited to present a showing that demonstrates unexpected results in increasing endogenous testosterone in various age groups, as well as increasing the testosterone/estrogen ratio in men and increasing testosterone levels in men while leaving estrogen levels relatively unaffected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to

Art Unit: 1614

37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 30, 2005


Phyllis G. Spivack
1614
**PHYLLIS SPIVACK
PRIMARY EXAMINER**